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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,936	03/16/2001	Tony N. Frudakis	210121.419C11	7264

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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,936

Applicant(s)

FRUDAKIS ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6-10, and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6-10 and 12-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments in Paper No. 14, filed March 19, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Claims 18-22 are under examination on the merits.

PRIORITY

3. It is acknowledged that priority document, U.S. Serial Number 08/585,392, discloses SEQ ID NO:16 and discusses the claimed invention as it is directed to any generic antibody (Pages 9-14). However, the priority document, U.S. Serial Number 08/585,392, does not disclose the claimed invention of antibodies as they specifically bind to the B305D polypeptide. It is re-iterated that the examined claims 18-22 will be granted the priority date of May 24, 2000, corresponding to U.S. Serial Number 09/577,505.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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6. This rejection is maintained with respect to claims 18-22, as recited in the previous office action Paper No. 11, mailed September 19, 2002.

7. It is acknowledged that Applicants traverse the said rejections of claims 18-22 by arguing that the "instant specification teaches the preparation of antibodies"... and "Example 7 puts this teaching into practice to generate antibodies to breast tumor antigen B305D" (Pages 2-3).

Further, Applicants' pointed support of "rabbit immunizations and B305D polyclonal antibodies showed immunoreactivity to B305D polypeptides" (Page 3, 1st ¶). It is acknowledged that the instant application discloses the claimed antibodies as being tested in an ELISA assay and used in immunohistochemical analysis of B305D expression in breast cancer and normal breast cancer specimens. Applicants' arguments have been considered and found to be unpersuasive due to the said arguments fail to support the claim that an isolated antibody binds specifically to B305D polypeptide (See ¶ 7 in Paper No. 11, mailed September 19, 2002). Although the polyclonal antibodies show immunoreactivity to B305D in ELISA assays, the pointed support does not disclose that the polyclonal antibodies do not bind to antigens that are not of B305D polypeptide. It is well known in the art that polyclonal antibodies have a propensity to recognize a variety of different antigenic sites including sites that are not related to the B305D polypeptide. In most common cases, polyclonal antibodies recognize other antigens in addition to the polypeptide used to generate them. This phenomenon usually results in high background staining in immunohistochemical analysis, the appearance of extract bands in Western Blots, or immunoreactivity to B305D and thereof in ELISA assays.

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8. Specific to claims 19-21, Applicants traverse on the grounds that the instant specification provides instructions for determining the percent identity of a particular sequence (pages 28-30) and one of ordinary skill in the art would readily appreciate that assays (such as an ELISA) can be used to determine if a polypeptide specifically binds to an antibody or not. Applicants' argument and pointed support have been found to be unpersuasive. It is reiterated that the specification does not reasonably provide enablement for an isolated antibody, or antigen-binding fragment thereof, that binds to a polypeptide having an amino acid sequence 80%, 90% or 95% identical to the amino acid sequence of SEQ ID NO:304. It is unclear as to how it would be possible to predict with accuracy that the immunological interactions correspond to an amino acid sequence with 80%, 90% or 95% identity to SEQ ID NO:304, respectively. Further, there is not any guidance as how a person skill in the art of making antibodies to distinguish immunologic interactions between an antibody to polypeptides that are similar to the polypeptide of SEQ ID NO:304 in an *in vivo* environment. Therefore, the applicant does not provide any disclosures within the specification that would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.
9. It is suggested that a declaration under 37 CFR 1.132 containing data directed to antibodies specifically binding to B305D but do not bind to antigens that are not of B305D polypeptide could be used to overcome the said lack of enablement rejection.

CLAIM REJECTIONS – 35 USC §102

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(e) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 18 - 22 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Xu et. al. (P/N 6,329,505).

12. This rejection is maintained with respect to Claims 18-22, as recited in the previous office action Paper No. 11, mailed September 19, 2002.

13. Applicants' argument that the instant applicant correctly claimed priority dating back to U.S. Serial Number 08/585,392, therefore, U.S. Patent No. 6,329,505 would not be considered prior art under 35 U.S.C. §102(e). Applicants' argument has been considered and found to be unpersuasive. In light of the discussion directed to the priority benefits of this instant application, the rejection claims 18 - 22 under 35 U.S.C. 102(e)(2) is maintained.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to

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37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION

16. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

19. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
5/20/03

John J. Mansch
JOHN J. MANSCH
5/20/03